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OTT-NIH
C/O EDWARDS ANGELL PALMER & DODGE LLP
PO BOX 55874
BOSTON, MA 02205

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| EXAMINER |
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CHEN, STACY BROWN

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1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/536,860 | Applicant(s) GOLDING, HANA | |
| | Examiner STACY CHEN | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,12-15,17,18,21 and 131-139 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,12-15,17,18,21 and 130-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/11/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and remarks filed submission filed on March 8, 2011 have been entered. Claims 1, 5, 7, 12-15, 17, 18, 21, 131-136 and new claims 137-139 are pending and under examination. Note that the claim listing of March 8, 2011 indicates that claims 137 and 138 were already presented in a previous claim listing, however, they appear to be newly introduced in the most recent response.

Response to Amendment

2. The rejection of claims 130, 132 and 136 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn in view of Applicant's amendment.

Claims Summary

3. The claims are drawn to a rapid (i.e., completed with 24 hours) vaccinia neutralization assay comprising:

- Incubating a mixture comprising at least one cell, a candidate antibody, and a labeled vaccinia virus that encodes a reporter gene encoding an enzyme;
- Detecting the activity of the enzyme within the cell, wherein a decrease in the enzyme activity (relative to a control) indicates that the candidate antibody decreases vaccinia virus invasion of the cell.

Specifically, the vaccinia virus is vSC56 or vSC8 having a reporter gene encoding β -gal under control of a late vaccinia promoter P11 or a synthetic E/L promoter. The candidate

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antibody is a monoclonal, a polyclonal or altered antibody. An altered antibody includes antibody fragments described on page 11, lines 13-16. The candidate agent associates with the cell or the virus. The Office interprets "associates with" to be equivalent to the antibody binding the invasin. Specifically, the cell is a mammalian cell, such as a human cell (e.g., lymphoid, pulmonary or intestinal).

The step of detecting the enzyme activity comprises measuring a change in the color or fluorescence of the substrate of the enzyme using, for example, an ELISA reader instrument. The method is in the format of a neutralization assay or a high throughput assay and may be performed in a 96-well plate. The method may also include quantitation of invasion of a cell by a virus using a standard curve, wherein r^2 of the standard curve is >0.9 . The method results are predictive or protection against viral lethality in vivo in a mouse model (e.g., SCID), and are comparable to results obtained with a PRNT neutralization assays.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(New Rejection) Claims 5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that vaccinia virus vSC56 and vSC8 are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the viruses. See 37 CFR 1.802. Access to the antibodies is required to practice the invention. The specification does not provide a repeatable method for making the antibodies without access to the hybridomas that produce them and it does not appear to be readily available material. The specification, in Example II, indicates that the viruses were generating in a laboratory.

Deposit of the antibodies in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

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that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 12-15, 17, 18, 21, 131, 136 and 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent 6,451,309, "Hooper") in view of Auewarakul et al. (Asian Pacific Journal of Allergy and Immunology, 2001, 19:139-144, cited in IDS filed 3/29/07, "Auewarakul") and Domínguez et al. (Journal of Immunological Methods, 1998, 220:115-221, "Domínguez"). Note that claims 5 and 7 are no longer included in this rejection because they are rejected for lack of enablement as a result of Applicant's amendment.

Hooper teaches the production and identification of vaccinia monoclonal antibodies for the purpose of therapeutic treatment (passive immunization) of vaccinia in humans (abstract). Hooper discloses that potential targets for poxvirus therapeutics, monoclonal antibodies, were generated in mice and tested for their ability to neutralize virus and protect mice from challenge (col. 2, lines 5-20).

It would have been obvious to have modified Hooper's method by using methods known in the art to improve the speed of the assay and also decrease the cost of performing plaque reduction neutralization testing. One would have been motivated to use a reporter virus in a neutralizing antibody assay using flow cytometry as a measurement tool, such as the assay described by Auewarakul in order to test the many antibodies of Hooper with greater speed and reduced cost (see abstract). Although Auewarakul's reporter virus is an HIV construct, it would have been obvious to have used Domínguez' green fluorescent protein (GFP) recombinant vaccinia virus that permits early detection of infected cells by flow cytometry (abstract). Domínguez uses the construct as an infection tag (page 116, first column, third full paragraph). One would have expected Domínguez' reporter virus to infect Hooper's cells (if not neutralized by antibodies) and express GFP, which would then be detected by flow cytometry.

As a further modification to the assay, it would have been obvious to have used an enzyme such as β -galactosidase instead of GFP. Domínguez discloses that a number of marker genes have been inserted in the vaccinia virus genome, and that their utility has been demonstrated in different experimental situations (thymidine kinase, guanine phosphoribosyl transferase, β -galactosidase, etc.), see Domínguez, pages 115-116, bridging paragraph. Although Domínguez opts to use GFP, it is clear that enzyme labels are well known in the art to be useful

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in assays where a detectable marker is expressed in virus-infected cells. On page 115, first column, Domínguez states:

Detection of virus-infected cells usually relies on the detection of viral proteins, using specific reagents such as antibodies. As an alternative, the use of convenient readily detectable marker genes has been suggested.

It would have been obvious to have substituted an enzyme label for GFP, since Domínguez generally teaches that detectable marker genes, including enzymes, have been suggested as convenient and readily detectable as opposed to antibodies. One would have had a reasonable expectation of success that the use of β -galactosidase, for example, would have worked as a detectable marker gene because it has been shown in the art to be expressed by vaccinia virus in infected cells (see Domínguez, pages 115-116, bridging paragraph).

With regard to the limitations of claims 18 and 21, that the cells be human (e.g., lymphoid), it would have been obvious to have used human cells in the method in order to reflect more accurately the infection of human cells by vaccinia. Auewarakul uses human PBMCs in their HIV-1 neutralization assay (see pages 140-141, bridging col.).

With regard to the limitation in claim 131 that the method results correlate with viral lethality in a mouse model in vivo, one would expect some degree of correlation between in vitro results and in vivo results. For example, it is usually through in vitro testing that candidate in vivo products are selected and tested further for efficacy. As to the mouse model being a SCID mouse model (claim 139), this limitation is not an active step of the claimed method, rather, it describes an inherent feature of the method. By following the suggestions of the prior art, one would have arrived at a method that has the same features observed by Applicant.

With regard to the limitation in claim 136 that the method provides results that are comparable to results obtained with a PRNT neutralization assays, the results are expected to be comparable, given that Auewarakul's reporter-virus flow cytometry method yielded comparable results to the standard infectivity reduction assay (see Auewarakul, abstract). Therefore, the invention would have been obvious to one of ordinary skill in the art at the time of the invention.

Response to Arguments

6. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that the instantly claimed assay has widespread and successful use by those in the pertinent art subsequent to the time of the invention. Applicant points to several literature references (see IDS filed 3/11/11) that purportedly highlight the usefulness of the assay compared with PRNT assays.
- In response to Applicant's arguments, it appears that Applicant is arguing commercial success of and long-felt need resolved by the present invention. Applicant must establish a nexus between the claimed invention and evidence of commercial success to support their contention of nonobviousness. The nexus designates a factually and legally sufficient connection between the evidence of commercial success and the claimed invention so that the evidence is of probative value in the determination of nonobviousness (see MPEP 716.03 I). As evidence, Applicant is relying on the use of the assay documented in the literature references cited. The references that highlight the usefulness of the assay compared with PRNT assays are co-authored by

- the instant inventors (Manischewitz et al., 2003, and Kennedy et al., 2009). As to other references that are not co-authored by the instant inventors, but which Applicant argues are evidence of the widespread use and success of the assay, those references merely indicate that they used the assay (Kennedy et al., Vaccine, 2009, and Kaufman et al., 2008), or compared Applicant's assay with other assays (PRNT and the author's own assay) and found the author's own assay's reproducibility to be lower than or comparable to PRNT and Applicant's assay (Haralambieva et al., 2008). Using Applicant's assay, and finding Applicant's assay to be comparable to PRNT in terms of reproducibility do not rise to the level of a factually and legally sufficient connection between the evidence of commercial success and the claimed invention such that the evidence is of probative value.
- With regard to long-felt need being resolved by the present invention, the Office does not find any evidence to that end. See MPEP 716.04.
 - Applicant argues that Hooper only discloses the PRNT assay and the observation that the PRNT assay did not always predict the protective efficacy of the antibodies being tested. Applicant argues the instantly claimed assay has the unexpected advantage of being predictive of viral lethality in vivo, evidenced by Zaitseva et al. (filed with IDS on 3/11/11).
 - In response, the Office is not relying on Hooper to teach all aspects of the instantly claimed invention. Hooper's teachings regarding the PRNT assay and its shortcomings are the basis for the motivation to modify Hooper's method.

- Regarding the unexpected advantage of the claimed invention to be predictive of viral lethality in vivo or protective efficacy in vivo, and reliance on the Zaitseva et al. reference, this argument is not persuasive because if one were to follow the suggestions of the prior art, one would have arrived at the claimed invention along with all of its advantages.
- Applicant argues that does not cure the deficiencies of Hooper because the instant invention requires that the assay be completed within 24 hours. Applicant notes that Auewarakul's method requires several days or longer to be completed. Applicant argues that since the PRNT assay requires 4-7 days to be completed, that Auewarakul's method offers no advantage over PRNT in terms of increasing the speed of the assay, as asserted in the rejection as a motivating factor. Applicant also argues that in terms of decreasing the cost (another motivating factor asserted in the rejection), Auewarakul's method uses flow cytometry, whose equipment is expensive and adds operating costs to laboratories.
- In response to Applicant's argument, Auewarakul's method was able to detect green fluorescence at day 2 (see page 141), which is an improvement in speed over PRNT. An improvement in the speed of the assay is reasonably expected to result in decreased cost in time, labor, etc. Further, Auewarakul observes that the results of their assay were comparable with another assay, infectivity reduction assay. Given that Hooper acknowledges that the PRNT assay was not always predictive of virus lethality, and that it was known in the art that other faster and less expensive methods were known, it would have been obvious to have used another assay that would at

least have increased the speed of the assay, reduced the cost of the assay, and minimally be comparable in terms of detecting infection.

- With regard to the Domínguez reference, Applicant argues that it cannot be relied upon because it does not teach the use of enzyme genes in the context of neutralization assay. Applicant argues that the mention of enzymes in the Domínguez reference, and the cross references provided by the Domínguez reference, are limited to the expression of enzymes in cloning vectors.
- In response to Applicant's argument, the context of Domínguez mentioning enzymes is that of enzyme labels being well known in the art to be useful in assays where a detectable marker is expressed in virus-infected cells. On page 115, first column, Domínguez states the following: "Detection of virus-infected cells usually relies on the detection of viral proteins, using specific reagents such as antibodies. As an alternative, the use of convenient readily detectable marker genes has been suggested." As outlined above, it would have been obvious to have substituted an enzyme label for GFP, since Domínguez generally teaches that detectable marker genes, including enzymes, have been suggested as convenient and readily detectable alternative to antibodies. One would have had a reasonable expectation of success that the use of β -galactosidase, for example, would have worked as a detectable marker gene because it has been shown in the art to be expressed by vaccinia virus in infected cells (see Domínguez, pages 115-116, bridging paragraph). Further, the cross references provided by Domínguez when mentioning enzymes are not in any way limiting the enzymes' uses to those disclosures.

- Applicant also argues that one would not have sought alternatives to the PRNT assay, despite its known disadvantages, because the PRNT assay was the "gold standard" in the art at the time of the invention.
- In response to Applicant's arguments, the Office acknowledges that the PRNT assay was, at the time of the invention, the "gold standard". However, there is no evidence that the PRNT assay being the "gold standard" would have completely stopped anyone from attempting improvements or inventing alternatives to it. Even though the PRNT assay was validated, it does not follow that innovation would cease in this important area of detection of virus infectivity.

7. Claims 132 and 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent 6,451,309, "Hooper") in view of Auewarakul et al. (Asian Pacific Journal of Allergy and Immunology, 2001, 19:139-144, cited in IDS filed 3/29/07, "Auewarakul") and Domínguez et al. (Journal of Immunological Methods, 1998, 220:115-221, "Domínguez"), as applied to claim 1 above, and further in view of Briskin et al. (US Patent 6,319,675, published November 20, 2001, filed November 24, 1999, "Briskin") and BD Biosciences (Introduction to Flow Cytometry: A Learning Guide, Manual Part Number: 11-11032-01, April, 2000, "the flow cytometry guide"). The claims require that the assay be a high throughput assay. The method is performed in a 96-well plate. These particular limitations are not taught by Hooper, Auewarakul or Domínguez.

However, it would have been obvious to have applied high throughput technology to the method taught by Hooper/Auewarakul/Domínguez in order to process more samples (e.g.,

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antibodies) in less time. Briskin's teachings are an example of the technology available at the time of the invention with regard to high throughput screening. Although Briskin's assays are directed to different products, the concept of screening large numbers of samples (in 96-well plates, for example) for potential agents that interfere with various binding partners was known (see col. 16, lines 42-54). Therefore, the invention would have been obvious to one of ordinary skill in the art at the time of the invention.

Applicant's arguments are addressed above with regard to the Hooper, Auewarakul and Domínguez references.

8. Claims 133 and 134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent 6,451,309, "Hooper") in view of Auewarakul et al. (Asian Pacific Journal of Allergy and Immunology, 2001, 19:139-144, cited in IDS filed 3/29/07, "Auewarakul") and Domínguez et al. (Journal of Immunological Methods, 1998, 220:115-221, "Domínguez"), as applied to claim 1 above, and further in view of BD Biosciences (Introduction to Flow Cytometry: A Learning Guide, Manual Part Number: 11-11032-01, April, 2000, "the flow cytometry guide"). The claimed method further comprises quantitation of invasion of a cell using a standard curve, wherein r^2 of the standard curve is >0.9 . These particular limitations are not taught by Hooper, Auewarakul or Domínguez.

However, it would have been obvious to have quantified the results of the method in order to have more accurate measurements of the various antibodies' neutralization capabilities. One would have followed the guidelines available to those of ordinary skill in the art, such as the flow cytometry guide. In order to quantitate the results, one would have to have a standard curve

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(see the flow cytometry guide, page 35). As for the r^2 being >0.9 , the ordinary artisan would have selected any optimal value subject to individual preference. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time of the invention.

Applicant's arguments are addressed above with regard to the Hooper, Auewarakul and Domínguez references.

9. Claims 137 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooper et al. (US Patent 6,451,309, "Hooper") in view of Auewarakul et al. (Asian Pacific Journal of Allergy and Immunology, 2001, 19:139-144, cited in IDS filed 3/29/07, "Auewarakul") and Domínguez et al. (Journal of Immunological Methods, 1998, 220:115-221, "Domínguez"), as applied to claim 1 above, and further in view of Chakrabarti et al. (Molecular and Cellular Biology, 1985, 5(12):3403-3409, "Chakrabarti"). The claims are directed to embodiments wherein the detecting of enzyme activity comprising measuring a change in the color or fluorescence of a substrate of the enzyme, and wherein the measuring is conducted using an ELISA reader instrument.

It would have been obvious to have detecting enzyme activity by measuring a change in color or fluorescence and using an ELISA reader instrument. Chakrabarti describes the detection of the expression of β -gal from vaccinia virus in cells by detecting a color change at a particular absorbance (see page 3404, top of second column). Although Chakrabarti does not mention using an "ELISA reader instrument", one would have had to have used an instrument to measure absorbance (see page 3404, bridging paragraph between first and second columns). Therefore,

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the claimed embodiments would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

10. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACY CHEN whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648